

For his Verified Complaint, Plaintiff United States of America, through Relator Kenny Loughner, alleges as follows:

1. Loughner brings this qui tam action as relator for the United States of America seeking statutory penalties, treble damages, and attorney fees pursuant to the False Claims Act, 31 U.S.C. §§ 3729, et seq., and to recover damages or other relief on the basis of Defendants' fraud and unjust enrichment.

The Parties

2. Plaintiff is the United States of America.
3. Relator is an individual who resides in Lorain County, Ohio.
4. Relator is the former manager of Defendant EMH Regional Medical Center's catheterization and electrophysiology laboratory.
5. Relator was employed at EMH's catheterization laboratory from September 1994 to October 31, 2005.
6. As a result of Relator's employment with EMH, Relator has first-hand knowledge of Defendants' pattern and practice of unbundling medical services, staging and up-coding, and falsifying medical records which resulted in Defendants' submission of possibly several thousand false claims for Medicare and Medicaid reimbursement.
7. Defendant EMH Regional Medical Center ("EMH") is an Ohio corporation with its principal place of business in Lorain County, Ohio.
8. Defendant North Ohio Heart Center, Inc. ("NOHC"), is an Ohio corporation with its principal place of business in Lorain County, Ohio.
9. Defendant Charles D. O'Shaughnessy is an individual who resides in the Northern District of Ohio.

10. Defendant Naim Farhat is an individual who resides in the Northern District of Ohio.

11. Defendants O'Shaughnessy and Farhat are cardiologists who practice at NOHC. They are known to Relator to be the cardiologists in that practice most responsible for the below-stated facts.

12. NOHC is a cardiology practice with multiple locations in Northern Ohio. It performs its clinical procedures at EMH.

13. All of the named parties benefited from the pattern and practice below-stated.

Jurisdiction

14. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a). because Plaintiff's Complaint is a civil action arising under the laws of the United States, the Plaintiff brings this Complaint as relator on behalf of the United States of America, and the Complaint includes claims over which this Court has supplemental jurisdiction.

15. This Court has personal jurisdiction over the parties to this suit pursuant to 31 U.S.C. § 3732(a) because one or more of the defendants can be found, resides, or transacts business in the Northern District of Ohio.

Venue

16. Venue is proper in the Northern District of Ohio pursuant to 28 U.S.C. § 1391(b) and (c) because one or more of the defendants reside or transacts business in the Northern District of Ohio and all defendants reside in Ohio.

Nature Of Suit And Material Evidence In Plaintiff's Possession

17. On August 18, 2006, The New York Times published an article, entitled Heart Procedure Is Off the Charts in an Ohio City (the “NYT Article”), which stated that Defendants are much more likely to steer patients toward angioplasty than any other cardiology practice in the country.

18. The NYT Article also pointed out that patients treated by Defendants are more likely to undergo multiple procedures which could, and would, usually be undertaken at one time.

19. Relator is an original source of information pursuant to 31 U.S.C. § 3730(e)(4)(B), and has based this Complaint upon information separate and distinct from what was reported in the NYT Article, as he personally observed or learned from other sources facts set forth below which demonstrate that Defendants were engaged in a scheme to defraud the federal government out of millions of dollars of money paid to EMH and NOHC through the Medicare and Medicaid programs.

20. The Defendants worked together to devise and implement a scheme whereby the cardiologists employed by NOHC were providing medical services that were unnecessary, excessive and/or improper at EMH’s facilities.

21. The performance of unnecessary, excessive, and/or improper medical procedures, namely of angioplasties, was carried out by NOHC cardiologists at EMH’s facility.

22. EMH provided the facilities for performance of the over-prescribed angioplasties and derived pecuniary benefits thereby.

23. Defendants O’Shaughnessy and Farhat were the biggest offenders in the use angioplasty procedures that were not necessary and inappropriately staged, and also in the

advising of patients to exaggerate symptoms to make sure that the procedures were covered by Medicare or Medicaid and in the outright falsification of medical records endemic at NOHC.

24. The over-prescription of angioplasties was done with the sole intention of enriching the Defendants, in part through reimbursement to Defendants through the Medicare and Medicaid programs.

25. Defendants also engaged in prohibited kick-backs among themselves.

26. The False Claims Act (“FCA”) provides that a person or group of persons are liable for knowingly presenting a false or fraudulent claim for payment to the United States government, using false records to get a false or fraudulent claim paid, or conspiring to defraud the United States government. 31 U.S.C. § 3729(a).

27. A person or group of persons acts “knowingly” for purposes of the FCA when they have actual knowledge of the falsity or fraudulent nature of the information, they act in deliberate ignorance of the truth or falsity of that information, or they act in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b).

28. A “claim” for purposes of the FCA is any request for money if any portion thereof comes from the United States government. 31 U.S.C. § 3729(c). Medicare and Medicaid claims are “claims” under the FCA.

29. The anti-kickback provisions relating to Medicare and Medicaid. 42 U.S.C. § 1320a-7b(b), prohibits any person or persons from making or accepting payment to induce or reward any person for referring Medicare-covered medical services. It provides in pertinent part:

(b) Illegal remunerations.

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$ 25,000 or imprisoned for not more than five years, or both.

Catheterization and Angioplasty

30. "Catheterization" refers to the insertion of a catheter into a major blood vessel and inserting the catheter up to the blood vessels surrounding the heart. It is the first step in a variety of cardiac procedures.

31. An "angiogram" is an imaging technique whereby a cardiologist takes an X-ray picture of the blood vessels servicing the heart. In order to develop the angiogram, a patient is injected with a "contrast medium" through the catheter which allows for visualization of the blood vessels in the X-ray picture.

32. "Angioplasty" is a procedure whereby a cardiologist either inflates a balloon at the site of blockage or inserts a stent into an occluded or blocked vessel in order to increase the flow of blood through that vessel. Angioplasties are done after an angiogram is performed to identify blocked blood vessels.

33. One angioplasty procedure may include the implantation of multiple stents, depending on how many blood vessels are identified after an angiogram as being blocked.

34. Angiograms and angioplasties are performed by cardiologists in a clinic setting where the patients are anesthetized.

35. It is routine, and the standard of care, for a cardiologist to approach every angiogram prepared to perform an angioplasty in the event that the angiogram indicates that angioplasty is required. Since the patient undergoing the angiogram is already sedated, and since the catheter which is used for both the angiogram and angioplasty is already in place, it is logical, economical, and fair for the patient to perform all of the procedures at the same time if at all possible.

36. Performing both an angiogram and all necessary stent insertions at one time is not only common in the medical field, but is required to be billed as a bundled medical procedure for purposes of Medicare reimbursement.

Staging and Unbundling Services

37. During the scope of Relator's employment, Relator observed a pattern and practice of Defendants' unbundling of angioplasty and angiogram services and deliberate "staging" of those unbundled procedures.

38. Relator has first hand knowledge that Defendants would schedule angiograms without preparing to perform angioplasty procedures (i.e. without indicating that the angiogram was being undertaken as "stent possible"), which had the effect of requiring patients to schedule a separate appointment for an angioplasty in the event a blockage was detected.

39. Relator also has first hand knowledge that Defendants would schedule angioplasties with knowledge that more than one stent should be implanted, but would deliberately insert fewer than the necessary number of stents, leaving blocked or occluded blood vessels to be stented at a later date.

40. This practice led Defendants to routinely schedule serial angioplasties, the usual frequency between procedures being one to three weeks later.

Falsification of Medical Records

41. Defendants had a pattern and practice of advising patients to complain of chest pain, whether or not the patients were experiencing chest pain, and then would present to the emergency room.

42. As a result of the patients' complaint of chest pain, on information and belief, those patients were immediately eligible for insurance or Medicare coverage for a catheterization.

43. On information and belief, even though these patients were presented as chest pain patients experiencing a medical emergency, the catheterizations which ultimately did take place were scheduled on a non-emergency basis.

44. Relator personally observed the individual physicians identified as Defendants herein routinely instruct EMH nurses and technicians involved in the procedures to record fictitious and non-existent complaints of chest pain (habitually when the patient was so sedated that complaint was not possible); record fictitious and non-existent "ST" changes on an echocardiogram; and to falsify other alleged cardiac complaint or symptoms in a deliberate attempt to justify the necessity of the angioplasty procedures to insurance companies and federally funded health programs such as Medicare and Medicaid.

45. In 2001 or 2002. Relator also has first hand knowledge that during interventional catheterization procedures, an NOHC doctor instructed a nurse to falsify documents and patient records on such frequency that the nurse requested that Relator not schedule the nurse for procedures which involved research studies because of her fear that the studies would not be accurate. In addition, the NOHC doctor also requested of Relator that the same nurse not be scheduled for any research angioplasty/stent procedures. Upon information and belief, the nurse

was not used because of her outspoken criticism of NOHC doctors and their blatant falsification of patient records in research cases to justify either the volume of angioplasty procedures or the inclusion of patients in research studies that didn't meet the criteria for the study.

Anthem Letter

46. On late 2004 or early 2005, Anthem Blue Cross and Blue Shield submitted a written objection and question about a particular case which involved a patient who had two medical procedures which were cardiac in nature and occurred within weeks of one another (the "Anthem Letter").

47. In response to the Anthem Letter, Dr. O'Shaughnessy instructed Drs. Daniel Blankenship and Scott Sheldon, both of NOHC, to research the issue of nephrotoxicity and to gather journal articles which tended to support nephrotoxicity as a justification for Defendants' performance of two separate angioplasty procedures in the face of Anthem's objection urging that both procedures should have been completed at the same time.¹ Dr. O'Shaughnessy instructed his colleagues to undertake this course of action without consulting the patient's medical records.

48. Defendants then transmitted their research to Don Sheldon, Vice President of Medical Affairs at EMH, who drafted a response letter to Anthem concerning the patient. Relator personally reviewed the letter.

49. There is no medical basis for NOHC's claim that nephrotoxicity concerns justify their practice of unbundling angioplasty procedures because the level of contrast medium used in

¹ In other words, the NOHC doctors were attempting to explain away their calculated staging and unbundling of medical procedures by claiming that the multiple procedures were necessary to avoid damage to a patient's kidneys by the contrast medium used in the procedures.

multiple-stent procedures was not enough to cause any damage to the vast majority of the patient population.

50. As a result of their response to the Anthem Letter, and the justification for staging the procedures set forth therein, Defendants continued to persuade EMH staff members that their staggering volume of angioplasty procedures were appropriate and continued in their scheme to unbundle medical procedures and submit false and fraudulent claims to Medicare and/or Medicaid.

Illegal Kickbacks

51. NOHC received a kickback of approximately \$1,500 per month from EMH's catheterization lab budget.

52. While employed at EMH, Relator asked his supervisor, Charlotte Wray, why NOHC was paid this monthly stipend. In response, Wray explained that the payment "looked like a kickback."

53. Wray further explained that the approximately \$1,500 monthly kickback was justified, on paper, with the explanation that NOHC was being reimbursed for costs it incurred when the scheduler from NOHC faxed a handwritten list of patients seen in the office of NOHC and who were to be scheduled in the EMH catheterization laboratory for a cardiac procedure.

54. Relator has personally observed the schedules prepared by NOHC. They were handwritten lists of patients prepared by the scheduler at NOHC which were faxed to the secretary at EMH who then entered the schedule into a word processor. In no way did the \$1500 monthly payments made by EMH to NOHC bear any relation to the work that the scheduler at NOHC performed by preparing a handwritten list of patient names on a piece of paper was faxed to EMH.

55. On information and belief, Dr. O'Shaughnessy personally collected a separate kickback from EMH's catheterization laboratory's budget under the pretense that this monthly payment of approximately \$5,000 per month was for Dr. O'Shaughnessy service as the clinical director and coordinator of the lab.

56. Relator has first hand knowledge that O'Shaughnessy rarely attended the committee meetings he was being paid to chair, such as the mortality and morbidity committee meetings and the cardiovascular committee meetings.

57. Relator is also aware that EMH received at least one "reimbursement" of approximately \$250,000 from the supplier of the drug coated stents Defendants used in the majority of the angioplasty procedures performed at EMH. That medical supplier's sales representative was extremely generous with the NOHC cardiologists, even going so far as to cater one of their Christmas parties.

Joint Venture –North Ohio Heart Lab at EMH

58. As further evidence of the defendants' continuing and escalating practice of performing unnecessary cardiac procedures, in 2004 EMH and NOHC began discussions of a jointly-owned or operated catheterization lab in which NOHC would get a greater reimbursement rate of the diagnostic procedures performed at EMH.

59. Upon information and belief, the purpose of the new catheterization lab was to increase the profit margin for all Defendants' because it would increase the visibility of the catheterization laboratory in the community and it would solidify the relationship between EMH and NOHC.

60. In light of an initial plan which contemplated the new laboratory's construction after EMH constructed its "Heart Tower", Dr. O'Shaughnessy and others at NOHC complained

and demanded that the catheterization lab construction be completed first. On information and belief, as soon as EMH learned that NOHC may have had discussions for the construction of the laboratory NOHC wanted with a rival hospital, Community Health Partners ("CHP"), EMH entered into the joint venture with NOHC, fast-tracked the demolition of the fourth floor of the existing EMH facility, and turned it into a catheterization laboratory that NOHC was so urgent to have in place.

61. In or about September of 2005 EMH and NOHC opened the product of their joint venture, called and marketed as the "North Ohio Heart Center at EMH" on the fourth floor of the hospital.

62. Relator was told by Dr. Sheldon of EMH and his supervisor Charlotte Wray that the doctors at NOHC would receive on the order of three times as much reimbursement from all of the diagnostic procedures performed in the new catheterization laboratory, which explained NOHC's rush to get the lab open.

63. Relator was also told by Dr. Sheldon of EMH and his director, Charlotte Wray, that EMH wanted to go forward with the joint venture to solidify EMH's relationship with NOHC.

64. The Joint Venture lab is not equipped to perform angioplasty, only angiograms, and so is guaranteed to continue to facilitate Defendants' practice of unbundling services.

Count One
[31 U.S.C. § 3729(a)(1)]

65. Plaintiff incorporates the foregoing as if fully stated herein.

66. As set forth above, Defendants have knowingly presented false or fraudulent claims for Medicare reimbursement by over-prescribing angioplasties, by unbundling and staging multiple angioplasties, and by falsifying medical records.

67. Plaintiff is entitled to a civil penalty of not less than \$5,000 and not more than \$10,000 for each false or fraudulent claim, as well as three times the amount of damages which the United States Government sustained due to Defendants' false or fraudulent claims.

Count Two
[31 U.S.C. § 3729(a)(2)]

68. Plaintiff incorporates the foregoing as if fully stated herein.

69. As set forth above, Defendants have knowingly made, used, and caused to be made or used false records and statements to get a false or fraudulent claim paid by Medicare reimbursement by instructing patients to complain of chest pains when they were experiencing no chest pains and instructing staff to record complaints of fabricated chest pain.

70. Plaintiff is entitled to a civil penalty of not less than \$5,000 and not more than \$10,000 for each false or fraudulent claim, as well as three times the amount of damages which the United States Government sustained due to Defendants' false or fraudulent claims.

Count Three
[31 U.S.C. § 3729(a)(3)]

71. Plaintiff incorporates the foregoing as if fully stated herein.

72. As set forth above, Defendants have conspired to defraud the United States Government by getting a false or fraudulent claim paid.

73. Plaintiff is entitled to a civil penalty of not less than \$5,000 and not more than \$10,000 for each false or fraudulent claim, as well as three times the amount of damages which the United States Government sustained due to Defendants' false or fraudulent claims.

Count Four
(Fraud)

74. Plaintiff incorporates the foregoing as if fully stated herein.

75. The above pattern and practice of Defendants of seeking reimbursement from health insurers, including Medicare and Medicaid, based upon diagnoses which were false and known to be false at the time they were made, and which Defendants intended health insurers to rely upon, have caused damage to Plaintiff.

76. Plaintiff is entitled to damages for Defendants' fraud as a result thereof.\

Count Five
(Unjust Enrichment)

77. Plaintiff incorporates the foregoing as if fully stated herein.

78. In the ways and for the reasons set forth above, Defendants have been unjustly enriched in the amount that they were compensated based upon their pattern and practice of submitting false claims for payment for unnecessary medical procedures.

WHEREFORE. Plaintiff requests this Court enter judgment in its favor on all counts, impose a penalty of not less than \$5,000 and not more than \$10,000 for each of Defendants' violations of the False Claims Act, to award Plaintiff three times the amount of damages sustained, to award Plaintiff its costs and attorney fees, and to award Plaintiff any other relief to which it is entitled.

~~Respectfully submitted,~~

**NOVAK ROBENALT & PAVLIK,
L.L.P.**

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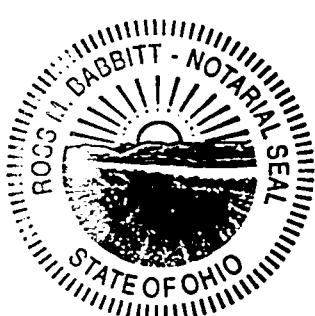
VERIFICATION

STATE OF OHIO)
) SS:
COUNTY OF LORAIN)

I, Kenny Loughner, hereby swear and affirm that the factual allegations contained in the above Verified Complaint are true and correct to the best of my knowledge, information, and belief.

Kenny Loughner

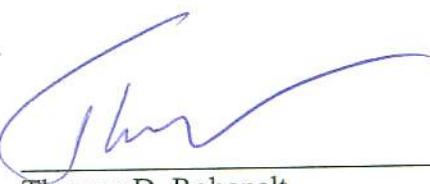
Sworn to and ascribed in my presence this 9th day of October, 2006.




Notary Public
Ross M. Babbitt, Esq.
My commission does not expire.

Jury Demand

A trial by jury is demanded for all issues so triable.



Thomas D. Robenalt